I. REMARKS:

A. Status of the Claims

Claims 1-18 were originally filed with the case. An Office Action requesting that Applicants select a single species for examination was mailed on October 7, 2005. Applicants timely responded, electing the species of AIT-082. Another Restriction Requirement was mailed on January 26, 2006, asserting that the application claimed three patentably distinct inventions and requiring that Applicants elect an invention for examination. Applicants timely responded, electing the Group I invention, directed to a method of treating dry eye.

Claims 1-6 were rejected in the Office Action mailed May 17, 2006. In a Response to Office Action filed on November 17, 2006, claims 1, 5, and 6 were amended, claim 4 was cancelled, and claims 7-18 were withdrawn as being directed to a non-elected invention. Claims 1-3,5 and 6 are rejected in the Final Office Action mailed on March 29, 2007. No claims are amended, cancelled or added herein. Thus, claims 1-3, 5 and 6 remain pending.

B. The Claims are Patentable Over Wallace and WO 00/32197

The Action rejects all claims as being obvious over Wallace and WO 00/32197. Wallace is said to teach the use of neurotrophic factors for the treatment of a number of eye disorders, including dry eye. The Action acknowledges that Wallace lacks a teaching of AIT-082. WO 00/32197 is said to teach that AIT-082 is a well-known neurotrophic factor. Thus, the Action asserts that it would have been obvious for a person skilled in the art to use AIT-082 for the treatment of dry eye. Applicants respectfully traverse.

Wallace appears to discuss compositions containing a neurotrophic factor and their use in the treatment of ocular disorders associated with ciliary ganglionic nerve cell degeneration. The neurotrophic factors discussed in Wallace are proteinaceous compounds characterized by having a pI in the range of 5.6 to 7.0 and a molecular weight of about 31.5 kD (Wallace, col. 2, lines 39-42). It is difficult to exploit peptide or protein molecules pharmaceutically due to bioavailability problems generally resident in the pharmaceutical administration of peptides (Spec. page 4, lines 11-13). Therefore, the methods of the present invention focus on the use of small molecule compounds that promote neuron regeneration or neurite outgrowth in a pharmaceutically acceptable vehicle to treat dry eye resulting from injury to corneal nerves. Wallace does not suggest the use of any compounds other than the neurotrophic factors themselves. That is, Wallace contains no suggestion to use small molecule compounds that promote neuron regeneration or neurite outgrowth would be useful in the compositions and methods described.

WO 00/32917 appears to discuss the use of neurotrophic factor stimulators to treat glaucomatous neuropathy and other retinal and optic nerve head degenerative diseases. Retinal and optic nerve head degenerative diseases are disorders occurring in the back of the eye. Dry eye resulting from injury to the cornea, however, is a disorder that occurs near the front of the eye. WO 00/32917 does not suggest that the compounds described therein can be used to treat disorders affecting the front of the eye, such as dry eye resulting from injury to the cornea. It is well known to the skilled artisan that, in order to deliver compounds to the eye for treatment of tissues at the back of the eye, one must typically deliver the active agent directly to the tissues at the back of the eye via intravitreal or juxtascleral injection, or the like. Most known compounds do not reach the tissues at the back of the eye via administration to the front of the eye. This is especially true of large molecules, such as proteins.

The Final Action argues that the claims of the instant application are drawn to the treatment of dry eye in general. This is not true. The present invention is directed to a method for treating dry eye resulting from injury to corneal nerves. The cornea is the transparent front part of the eye that covers the iris, pupil and anterior chamber. The cornea has unmyelinated nerve endings that are sensitive to touch, temperature and chemicals. The cornea receives nutrients from the tear fluid on its outer layer, the aqueous humor on its inner layer and from neurotrophins supplied by corneal nerve fibers. Thus, treatment of dry eye resulting from injury to corneal nerves will typically occur via topical administration of a composition containing the active agent.

According to the Supreme Court's recent decision in *KSR International Co. v. Telefax Inc. et al.*, 550 U.S. (2007), a finding of obviousness still requires a showing that there was a reason to combine the elements of cited references. The May 3, 2007, memorandum to the patent examining corps further emphasized that the PTO examiner must "identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed. The Federal Circuit recently underscored the Supreme Court's acknowledgement of the importance of identifying "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does" in an obviousness determination. *Takeda Chemical Industries, Ltd. v. Alphapharm PTY, Ltd.*, slip opinion, June 28, 2007. It is submitted that the Action has failed to provide a reason the skilled artisan would have combined the teachings of the cited references to arrive at the claimed invention.

In light of the foregoing arguments, Applicants respectfully request that the obviousness rejection based upon Wallace and WO 00/32917 be withdrawn.

C. Conclusion

This is submitted to be a complete response to the outstanding Final Office Action. Based on the foregoing arguments, the claims are believed to be in condition for allowance; a notice of allowability is therefore respectfully requested.

The Examiner is invited to contact the undersigned attorney at (817) 551-4321 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

/Teresa J. Schultz #40,526/

Teresa J. Schultz
Reg. No. 40,526
Attorney for Applicants

ALCON RESEARCH, LTD.
6201 S. Freeway, Q-148
Fort Worth, TX 76134-2099
(817) 551-4321

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